Remarks

Amendments to Claims

Claims 40, 47 and 54 are amended for clarity. Claims 44, 51, and 58 are amended to recite detecting "binding of the test compound to the polypeptide using an antibody." The specification supports this amendment at page 53, line 26 - page 54, line 15, as discussed in more detail below.

The amendments do not add new matter.

Amendment to Specification

As requested in the Office Action, the specification is amended to update the priority information.

ATCC deposit

Accompanying this paper is a copy of the deposit declaration for ATCC Deposit PTA-1640 which was filed in application Serial No. 09/561,763; the '763 application claims priority to Serial No. 09/431,367.

Rejection of Claims 40-58 Under 35 U.S.C. § 112

Claims 40-58 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. To advance prosecution, claims 45, 46, 52, and 53 have been canceled. Applicant respectfully traverses the rejection of claims 40-44, 47-50, and 54-58.

The pending claims are directed to binding assays. The previous Office Action contended that several recitations in the claims constituted new matter. The Final Office Action contends that the support Applicant provided for these claims is not with respect to binding assays *per se*. This is an overly narrow view of the specification's disclosures. The specification is addressed to one of skill in the art and must be considered as a whole when determining whether the written description requirement is met. *In re Wright*, 866 F.2d 422, 425, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989).

contacting a "sample" comprising a polypeptide (claims 40, 47, 54)

Independent claims 40, 47, and 54 recite, *inter alia,* contacting a "sample" comprising a polypeptide." The word "sample" is a generic term which does not require *ipsis verbis* support in the specification. Originally filed dependent claims 42, 49, and 56 recite various types of contacted samples ("wherein the sample is an isolated polypeptide, a membrane-bound form of an isolated polypeptide or a cell comprising the polypeptide"), which is sufficient to support the generic term "sample."

"a polypeptide comprising a fragment of at least 15 contiguous amino acids" (claim 54)

Claim 54 recites a polypeptide "comprising a fragment of at least 15 contiguous amino acids." The specification teaches that the invention provides assays for screening candidate or test compounds which bind to a TWIK protein or polypeptide or "biologically active portion [*e.g.*, fragment] thereof." Specification at page 50, lines 19-21 (emphasis added). "Fragments," according to the specification, include fragments comprising "at least 15 amino acids." See page 7, lines 5-10. The specification also teaches that "A biologically active portion of a TWIK protein can be a polypeptide which is, for example, 10, 25, 50, 100, 200, 313, 332, or 499 amino acids in length."

Specification at page 28, lines 29-31. One of skill in the art, reading the specification as a whole, would readily understand that the claimed binding assays could be carried out using polypeptide fragments comprising at least 15 amino acids of the recited polypeptides.

"polypeptide further comprises heterologous sequences" (claims 41, 48, and 55)

The specification teaches "proteins of the present invention or biologically active portions thereof, can be operatively linked to a non-TWIK polypeptide (*e.g.,* heterologous amino acid sequences)." Page 7 at lines 23-24. The specification also teaches, "TWIK proteins can be used as 'bait proteins' in a two-hybrid assay or three-hybrid assay . . . to identify other proteins, which bind to or interact with TWIK." Page 54, lines 32-37. The specification describes the two-hybrid system: "in one construct, the gene that codes for a TWIK protein is fused to a gene encoding the DNA binding domain of a known transcription factor (*e.g.,* GAL-4)." GAL-4 is a non-TWIK heterologous sequence. Thus, when considered as a whole, the specification adequately describes polypeptides comprising heterologous sequences for use in binding assays.

"immunoassay" (claims 44, 51, and 58)

The Final Office Action contends the specification does not support the general concept of an "immunoassay." Final Office Action at page 4 ¶ 1. Applicants disagree; however, to advance prosecution, claims 44, 51, and 58 have been amended to recite "detecting binding of the test compound to the polypeptide using an antibody." The specification supports this amendment at page 53, line 26 - page 54, line 15:

> Binding of a test compound to a TWIK protein, or interaction of a TWIK protein with a target molecule in the presence and absence of a candidate compound, can be accomplished in any vessel suitable for containing the

> reactants . . . Other techniques for immobilizing proteins on matrices can also be used in the screening assays of the invention. For example, either a TWIK protein or a TWIK target molecule can be immobilized utilizing conjugation of biotin and streptavidin . . . Alternatively, antibodies reactive with TWIK protein or target molecules but which do not interfere with binding of the TWIK protein to its target molecule can be derivatized to the wells of the plate, and unbound target or TWIK protein trapped in the wells by antibody conjugation. Methods for detecting such complexes, in addition to those described above for the GST-immobilized complexes, include immunodetection of complexes using antibodies reactive with the TWIK protein . . . .

When read as a whole, the specification adequately supports the recitations of claims 40-44, 47-50, and 54-58. Please withdraw the rejection.

Respectfully submitted,

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